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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/590,884 06/09/00 HAWKINS

E 341.014US1

021186 HM22/0424
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EXAMINER

CHAUDHRY, M

ART UNIT

PAPER NUMBER

1623

DATE MAILED:

04/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/590,884

Applicant(s)

HAWKINS ET AL.

Examiner

Mahreen Chaudhry

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-34 are indefinite with regard to the term “an organic compound” since it is unclear what specific organic compounds are to be utilized in the recited methods and kits. The term “organic compound” is broad and encompasses more than the specification could possibly support.

Claims 1-3 and 22-24 are indefinite with regard to “an organic compound that reduces luminescence...by at least about 10 fold...” It appears that the reduction in luminescence would be dependent on the concentration of the organic compound, however, no specific concentrations are recited in the claims. It is therefore unclear how “the presence of an organic compound” at any concentration could decrease luminescence by the specific amount recited in the claims.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-3, 8-12, 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 07067696A published by Mitoma et al. Mitoma et al. disclose a method of reducing background luminescence by treatment of haem and peroxidase with luminol and hydrogen peroxide in the presence of organic compounds such as citric acid which reduce background luminescence and increase sensitivity of measurement (abstract). Mitoma et al. do not expressly disclose the source of background luminescence or an amount by which such luminescence is reduced. However, it would have been obvious to one having ordinary skill in the art to have reduced background luminescence from any source using an organic compound as taught by Mitoma et al. since Mitoma et al. teach a general method of reducing background luminescence with organic compounds. It would additionally have been obvious to one having ordinary skill in the art to have reduced background luminescence by a desired amount by utilizing an appropriate quantity of an organic compound.

5. Claims 1-3, 8-31 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,629,168 issued to Kricka. Kricka discloses that the presence of specific organoboron compounds enhance chemiluminescence in the reaction involving luminol, hydrogen peroxide and peroxidase. Kricka discloses that the presence of the organoboron compounds increases the signal:background ratio in chemiluminescent reactions and that improving the signal:background ratio is important in improving the sensitivity of the assay (Column 3, Lines 50-65). Kricka additionally discloses that the concentration of the enhancer as between 0.01 uM and 4 M (Column 6, Lines 25-31). Kricka teaches a kit including luminol,

peroxidase and an organoboron enhancer (Column 4, Lines 58-60; Column 14, Lines 19-33).

Kricka further discloses that the signal:background ratio increased with increasing concentration of specific organoboron compounds (Column 7, Table 1). Kricka teaches that the improvement in signal:background ratio was attributable to the reduction in background light emission by specific organoboron compounds (Column 8, Lines 18-24). Kricka does not expressly teach the reduction of background light emission from any specific source, however, it would have been obvious to one having ordinary skill in the art to have utilized the method taught by Kricka for reducing background luminescence from any source and thus increase luminescent assay sensitivity since Kricka teaches a general process for increasing the signal:background ratio and decreasing background.

6. Claims 1-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,814,471 issued to Wood. Wood discloses a method for improving the kinetics of light production from luciferase activity. Wood discloses that the presence of thiol reagents including dithiothreitol results in a decrease in peak intensity and an increase in the total light emitted during a luciferase reaction (Column 5, Lines 52+; Column 8, Lines 51-63). Wood discloses test kits including a luciferase-luciferin composition, ATP, a thiol reagent and a buffer solution which may be combined in a single container or in several containers (Column 10, Lines 39-67). Wood further discloses that a luciferase composition with improved kinetics of light production includes an aqueous solution comprises beetle luciferase, CoA, a thiol reagent at a concentration between 10 and 100 mM and peak-intensity reducing compounds (Column 5, Lines 37-45; Column 13, Lines 24-35). Wood teaches that the luciferase assay may be conducted using cells

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(Column 9, Lines 32-48). Wood does not expressly disclose that the sensitivity of the assay is increased by reducing luminescence due to autoluminescence, luminogenic molecules and independent of the presence of analyte. However, Wood does disclose that the presence of thiol reagents results in a decrease in the peak intensity of light. It would therefore have been obvious to one having ordinary skill in the art to have utilized thiol reagents such as those taught by Wood to increase assay sensitivity since Wood teaches that thiol reagents decrease peak intensity and improve the kinetics of light production. Wood does not specifically disclose assays include Renilla luciferase or Cypridina luciferase, however, Wood does teach the use of beetle (firefly) luciferase and since both Renilla luciferase and Cypridina luciferase are well-known in the art, it would have been obvious to one having ordinary skill in the art to have utilized either Renilla luciferase or Cypridina luciferase in the method taught by Wood.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent 5,106,732 issued to Kondo et al. discloses a method of increasing the sensitivity of luminescent assays by the addition of sulfur containing organic compounds.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mahreen Chaudhry whose telephone number is (703) 605-1200. The examiner can normally be reached on Monday – Friday (8:30-5:00).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached on (703) 308-1701 . The official fax phone number for the organization where this application is proceeding or assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

mc
April 18, 2001



**RALPH GITOMER
PRIMARY EXAMINER
GROUP 1200**